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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/956,004      | 09/20/2001  | Patrick J. Dillon    | PB324D1             | 1504             |

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HUMAN GENOME SCIENCES INC  
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ROCKVILLE, MD 20850

EXAMINER

LY, CHEYNE D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

9

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/956,004

Applicant(s)

DILLON ET AL.

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-42 and 64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34, 37, 39, 41, and 64 is/are allowed.
- 6) ☒ Claim(s) 35, 36, 38, 40, and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicants' arguments in Paper No. 7, filed April 02, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. It is acknowledged that under *In re Ochiai* and *In re Brouwer* if any of the claims of Group I (claims 34-42) are found allowable, claim 64 will be rejoined and examined for patentability.
3. Claims 34-42 and 64 are examined on the merits.

**CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 38, 40, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. This rejection is maintained with respect to claims 38, 40, and 42, as recited in the previous office action Paper No. 6, mailed January 02, 2003.
6. Specific to claims 40 and 42, it is acknowledged that the pointed to citation in the specification discloses that a series of nucleotides being operably linked. However, the pointed to citation and the specification do not support that the specification discloses nucleotides being operably associated as stated in claims 40 and 42.

7. It is well known in the art of molecular biology at the time of the invention that nucleic acids operably linked through standard 3'-5' phosphodiester bonds to a vector DNA molecule (page 1, lines 17-18). The phrase "operably associated" is vague and indefinite because it is unclear what criteria are being used to consider polynucleotides as being "operably associated" (i.e. being adjacent via phosphodiester bonds or binding nucleotide sequence via thermal dynamic forces). Applicants can resolve this issue by particularly pointing out the criteria that is being used to determine polynucleotides are "operably associated." Clarification of the metes and bounds of the instant claims is required.
8. Specific to claim 38, line 1, the phrase "sequence complementary" causes to the claim to be vague and indefinite because it is unclear what criteria are being used to consider that the claimed nucleic acid is complementary to the entirety of the nucleotide of sequence of claim 34. It is acknowledged that Applicants have further limited the sequence of claim 34 to the entirety of the nucleotide sequence, however, such limitation does not resolve the issue of the term "complementary" being vague and indefinite. The issue remains that it is unclear what criteria are being used to consider the claimed nucleic acid sequence to be complementary to the entirety of the nucleotide of sequence of claim 34. Further, it is noted that claim 34 from which claim 38 depends, limits SEQ ID: 65 to nucleotides 2889-1915. Clarification of the metes and bounds of the instant claims is required. It is suggested that Applicants could resolve the above vague and indefinite issue by amending claim 38 to include the phrase "fully complementary."

**CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH**

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 35, 36, 40, and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.
11. This rejection is maintained with respect to claims 35, 36, 40, and 42, as recited in the previous office action Paper No. 6, mailed January 02, 2003.
12. Specific to claims 35 and 36, Applicants agree that the phrase "heterologous sequences" have been defined in cited textbook. Applicants' argument have been considered and found to be unpersuasive because citing a definition in a textbook does not resolve the issue that the limitation was not disclosed as filed.
13. Specific to claims 40 and 42, it is acknowledged that the pointed to citation in the specification does support that operable linkage or association has written disclosure as filed. However, the pointed to citation and the specification do not support that the specification discloses the operable association of a "heterologous" regulatory sequence, which is considered to be new matter.

#### **CLAIM REJECTIONS - 35 USC § 102**

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in:

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- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claim 38 is rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Valenuela et al. (US PN 5,814,478).
16. This rejection is maintained with respect to claim 38, as recited in the previous office action Paper No. 6, mailed January 02, 2003.
17. Valenuela et al. (US PN 5,814,478) teaches an isolated nucleic acid molecule set forth in SEQ ID NO:31 comprising a nucleotide sequence encoding a polypeptide having the MuSK-activating activity of human agrin. Consistent with the scope of claim 38, the fragment of SEQ ID NO:31 representing nucleotides 457-463 of Valenuela et al. is complementary to the fragment representing nucleotides 2459-2465 (CCAGTCA) of SEQ ID NO:65 of this instant case. (See ¶ 7 of the above discussion).
18. It is suggested that Applicants could overcome this prior art rejection by amending claim 38 to include the phrase "fully complementary."
19. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

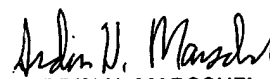
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### CONCLUSION

21. Claims 34, 37, 39, 41, and 64 are allowed.
22. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.
25. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
6/9/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER